15. (Amended) The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size [selected from the group consisting] of less than about 400 nm[, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm].

Claim 18, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

Claim 19, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

Claim 20, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

Claim 21, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

Claim 22, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

23. (Amended) A freeze-dried powder aerosol composition comprising aggregates of nanoparticulate drug particles, wherein:

(a) the aggregates of freeze-dried drug particles [have a respirable particle size] <u>are less than or equal to about 100 microns in diameter</u>;

(b) the nanoparticulate drug particles comprise a poorly soluble crystalline drug, have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface thereof.

26. (Amended) The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size [selected from the group consisting] of less than about 400 nm[, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm].

Claim 29, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

a10

Claim 30, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

a11

Claim 31, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

a12

Claim 32, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

a13

Claim 33, line 2, delete "MMAD" and insert therefor --mass median aerodynamic diameter--.

a14

35. (Amended) A dry powder nanoparticulate aerosol composition for use in a propellant-based pMDI comprising

a15

(a) aggregates of a nanoparticulate poorly soluble crystalline drug, wherein the drug has a surface modifier adsorbed on the surface thereof, and the drug has an effective average particle size of less than about 1000 nm, wherein the aggregates [have a respirable size] are less than or equal to about 100 microns in diameter, and

(b) a non-aqueous propellant.

37. (Amended) A nanoparticulate aerosol composition for use in a propellant-based pMDI comprising:

a16

(a) a nanoparticulate poorly soluble crystalline drug, wherein the drug has a surface modifier adsorbed on the surface thereof, and the drug has an effective average particle size of less than about 1000 nm, [and]

(b) essentially each droplet of the aerosol comprises at least one nanoparticulate drug particle, wherein the droplets of the aerosol generated by the pMDI have a diameter of less than or equal to about 100 microns, and

(c) a non-aqueous propellant.

40. (Amended) A method of making a dry powder nanoparticulate drug composition comprising:

(a) forming an aqueous nanoparticulate dispersion of a poorly soluble drug, wherein the dispersion comprises crystalline drug particles and a surface modifier adsorbed on the surface thereof, wherein the drug particles have an effective average particle size of less than about 1000 nm;

(b) spray-drying the nanoparticulate dispersion to form a dry powder of aggregates of the nanoparticulate drug and surface modifier particles, wherein the aggregates [are of a respirable size] have a diameter of less than or equal to about 100 microns.

42. (Amended) A method of making a dry powder nanoparticulate drug aerosol formulation comprising:

(a) milling under non-pressurized conditions a poorly soluble crystalline drug and a surface modifier in a non-aqueous medium having a high boiling point to obtain a nanoparticulate drug composition having an effective average particle size of less than about 1000 nm, and

(b) evaporating the non-aqueous medium to obtain a dry powder of aggregates of drug and surface modifier particles, wherein the aggregates [are of a respirable size] have a diameter of less than or equal to about 100 microns.

43. (Amended) A method of making a nanoparticulate drug aerosol formulation comprising:

(a) milling under pressurized conditions a poorly soluble crystalline drug and a surface modifier in a non-aqueous medium; and

(b) evaporating the non-aqueous medium to obtain a dry powder of aggregates of drug and surface modifier particles, wherein the aggregates [are of a respirable size] have a diameter of less than or equal to about 100 microns.

44. (Amended) A method of making a dry powder nanoparticulate drug composition comprising:

(a) forming an aqueous nanoparticulate dispersion of a poorly soluble drug, wherein the dispersion comprises crystalline drug particles and a surface modifier adsorbed on the surface thereof, wherein the drug particles have an effective average particle size of less than about 1000 nm;

(b) freeze-drying the nanoparticulate dispersion to form a dry powder of aggregates of the nanoparticulate drug and surface modifier particles, wherein the aggregates [are of a respirable size] have a diameter of less than or equal to about 100 microns.

Please add the following claims.

--51. The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.

52. The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.

53. The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.

54. The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.

55. The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.

56. The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.